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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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EXAMINER
KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
2836	

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,750	ELIA, JAMES P.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-235* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-235* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 6, 7, drawn to method for producing a tooth comprising administration of a growth factor, classified in class 424, subclass 85.1.
2. Claims 6, 8, drawn to method for producing bone comprising administration of a growth factor, classified in class 424, subclass 85.1.
3. Claims 9-12, drawn to method for producing a tooth comprising producing a bud with a growth factor and then administering said bud to a patient, classified in class 424, subclass 520.
4. Claims 9, 11, 13, 14, drawn to method for producing bone comprising producing a bud with a growth factor and then administering said bud to a patient, classified in class 424, subclass 520.
5. Claims 9, 10, drawn to method for producing hard tissue using gene therapy, classified in class 514, subclass 44.
6. Claims 15, 16, drawn to method for producing mesodermal tissues comprising administering a growth factor, classified in class 424, subclass 85.1.
7. Claims 15, 17, drawn to method for producing ectodermal tissue comprising administration of a growth factor, classified in class 424, subclass 85.1.

8. Claims 18, 20, 21, drawn to method for producing mesodermal tissue comprising producing a bud with a growth factor and than administering the bud to a patient, classified in class 424, subclass 520.

9. Claims 18, 20, 22, drawn to method for producing ectodermal tissue comprising producing a bud with a growth factor and administering the bud to a patient, classified in class 424, subclass 520.

10. Claims 18, 19, drawn to method for producing soft tissue using gene therapy, classified in class 514, subclass 44.

11. Claims 23, 24, 25, 27, drawn to method for producing tooth bud using gene therapy, classified in class 435, subclass 325.

12. Claims 23, 24, 26, 28, drawn to method for producing bone bud using gene therapy, classified in class 435, subclass 325.

13. Claims 29, 30, drawn to method for reviving dead brain tissue comprising administering a growth factor to form arteries, classified in class 424, subclass 85.1.

14. Claims 31, 34, drawn to method for reviving dead tissue comprising administering a growth factor to form arteries and a gene to stop artery growth, classified in class 514, subclass 44.

15. Claim 32, drawn to method for reviving dead tissue comprising administering a growth factor to form arteries and a growth factor to stop artery growth, classified in class 424, subclass 85.1.

16. Claim 33, drawn to method for reviving dead tissue comprising administering a growth factor to form arteries and an extracellular matrix to stop artery growth, classification dependent upon structure of matrix.

17. Claims 31, 35, drawn to method for reviving dead tissue comprising administering a growth factor to form arteries and a gene to stop artery growth wherein the dead tissue is heart tissue, classified in class 514, subclass 44.

18. Claims 36-40, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, classification dependent upon structure of recited "genetic material".

19. Claims 36-39, 41, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, classification dependent upon structure of recited "genetic material".

20. Claims 36-39, 42, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells and genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, classification dependent upon structure of recited "genetic material".

21. Claim 43, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a gene to stop muscle growth, classification dependent upon structure of recited "genetic material".

22. Claim 43, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a gene to stop muscle growth, classification dependent upon structure of recited "genetic material".

23. Claim 43, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells and genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a gene to stop muscle growth, classification dependent upon structure of recited "genetic material".

24. Claim 44, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a growth factor to stop

muscle growth, classification dependent upon structure of recited "genetic material".

25. Claim 44, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a growth factor to stop muscle growth, classification dependent upon structure of recited "genetic material".

26. Claim 44, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells and genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting a growth factor to stop muscle growth, classification dependent upon structure of recited "genetic material".

27. Claim 45, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting an extracellular matrix to stop muscle growth, classification dependent upon structure of recited "genetic material".

28. Claim 45, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing genes adjacent to the dead portion

to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting an extracellular matrix to stop muscle growth, classification dependent upon structure of recited "genetic material".

29. Claim 45, drawn to method for replacing a dead portion of a pre-existing organ in a patient comprising placing cells and genes adjacent to the dead portion to grow muscle, and placing genetic material adjacent to the dead portion to grow new arteries, and further comprising inserting an extracellular matrix to stop muscle growth, classification dependent upon structure of recited "genetic material".

30. Claims 46, 47, 49-54, drawn to live heart organ, classified in class 530, subclass 325.

31. Claims 46, 48, drawn to live brain organ, classified in class 530, subclass 325.

32. Claims 55, 56, 63 drawn to method for treating a burn wound comprising administering a growth factor, classified in class 424, subclass 85.1.

33. Claims 55, 57-63, drawn to method for method for treating a burn wound using gene therapy, classified in class 514, subclass 44.

34. Claims 64, 66-67, 69, 71-74, 77, drawn to method of forming heart tissue comprising providing a cell, adding growth factor to dedifferentiate, redifferentiate, and cause morphogenesis, classified in class 435, subclass 325.

35. Claims 64, 66, 68, 69, 71-74, 77, drawn to method of forming artery tissue comprising providing a cell, adding growth factor to dedifferentiate, redifferentiate, and cause morphogenesis, classified in class 435, subclass 325.

36. Claims 64, 66, 69-74, 77, drawn to method of forming pancreatic Islet cells comprising providing a cell, adding growth factor to dedifferentiate, redifferentiate, and cause morphogenesis, classified in class 435, subclass 325.

37. Claims 64, 65, drawn to method of forming tissue comprising providing a cell, adding growth factor to dedifferentiate, redifferentiate, and cause morphogenesis, wherein a genetic switch (gene therapy) is used, classification dependent upon nature of genetic switch.

38. Claims 75, 76, drawn to method of forming tissue comprising providing a cell, adding growth factor to dedifferentiate, redifferentiate, and cause morphogenesis, and then replanting the tissue in a patient 424, subclass 520.

39. Claims 78, 79, drawn to method of forming tissue comprising providing a germinal cell, adding growth factor to differentiate and cause morphogenesis, wherein a genetic switch (gene therapy) is used, classification dependent upon nature of genetic switch.

40. Claims 78, 80-83, drawn to method of forming tissue comprising providing a germinal cell, adding growth factor to differentiate and cause

morphogenesis, wherein the tissue is formed in vivo, classified in class 424, subclass 85.1.

41. Claims 78, 80-82, 84, 85, drawn to method of forming tissue comprising providing a germinal cell, adding growth factor to differentiate and cause morphogenesis, wherein the tissue is formed ex vivo or in vitro, classified in class 435, subclass 325.

42. Claims 86-90, drawn to method of forming a germinal cell comprising providing a cell and adding growth factor and, optionally, cell culture components, to cause dedifferentiation, classified in class 435, subclass 325.

43. Claims 91, 92, drawn to method of forming a germinal cell comprising providing a cell and adding growth factor and enhancers or promoters (gene therapy elements) to cause dedifferentiation, classified in class 514, subclass 44.

44. Claims 93, 94, 97-101 drawn to method of treating diabetes comprising administering a growth factor gene, classified in class 514, subclass 44.

45. Claims 93, 95, drawn to method of treating diabetes comprising administering a growth factor to a pancreas, classified in class 424, subclass 85.1.

46. Claims 93, 96, drawn to method of treating diabetes comprising administering a growth factor to a kidney, classified in class 424, subclass 85.1.

47. Claims 102, 103, drawn to hybrid organ, classified in class 435, subclass 347.

48. Claims 104, 105, 112-117, drawn to method of correcting avascular necrosis comprising administering a growth factor to regrow blood vessel, classified in class 424, subclass 85.1.

49. Claims 104, 106, 112-117, drawn to method of correcting avascular necrosis comprising administering a growth factor to regrow bone, classified in class 424, subclass 85.1.

50. Claims 104, 112-117, drawn to method of correcting avascular necrosis comprising administering a growth factor to regrow bone and blood vessel, classified in class 424, subclass 85.1.

51. Claims 104, 105, 107-111, 115-117, drawn to method of correcting avascular necrosis comprising administering a gene to regrow blood vessel, classified in class 514, subclass 44.

52. Claims 104, 106-111, 115-117, drawn to method of correcting avascular necrosis comprising administering a gene to regrow bone, classified in class 424, subclass 85.1.

53. Claims 104, 107-111, 115-117, drawn to method of correcting avascular necrosis comprising administering a gene to regrow bone and blood vessel, classified in class 424, subclass 85.1.

54. Claims 118-120, 122, drawn to method of growing an organ in a patient comprising administering a gene to a location, classified in class 514, subclass 44.

55. Claims 118, 121, 122, drawn to method of growing an organ in a patient comprising administering a growth factor, classified in class 424, subclass 85.1.

56. Claims 123-125, 127-131, drawn to method of growing a suborgan comprising Islet cells, said method comprising administering genes, classified in class 514, subclass 44.

57. Claims 123-125, 127-128, 132, drawn to method of growing a suborgan comprising neurons, said method comprising administering genes, classified in class 514, subclass 44.

58. Claims 123-125, 127, 128, 133, drawn to method of growing a suborgan comprising dermis, said method comprising administering genes, classified in class 514, subclass 44.

59. Claims 123, 126, 127-131, drawn to method of growing a suborgan comprising Islet cells, said method comprising administering growth factor, classified in class 514, subclass 44.

60. Claims 123-125, 127-128, 132, drawn to method of growing a suborgan comprising neurons, said method comprising administering growth factor, classified in class 514, subclass 44.

61. Claims 123-125, 127, 128, 133, drawn to method of growing a suborgan comprising dermis, said method comprising administering growth factor, classified in class 514, subclass 44.

62. Claims 134-136, 138-143, 145-147, drawn to method of growing an organ or suborgan outside of a body comprising administering genes, classified in class 435, subclass 69.1.

63. Claims 134, 137-141, 144-147, drawn to method of growing an organ outside of the body comprising administering growth factor, classified in class 424, subclass 85.1.

64. Claims 148, 149, 151-157, 159, 161-163, drawn to method of growing a tooth in the mouth of a patient comprising administering a gene in the mouth, classified in class 514, subclass 44.

65. Claims 150, 158, 160, 161, 164, drawn to method of growing a tooth in the mouth of a patient comprising administering a gene and a growth factor in the mouth, classified in class 514, subclass 44.

66. Claims 165, 166, drawn to method of growing an organ comprising providing a cell and inserting a gene into the cell, classified in class 435, subclass 325

67. Claims 167-169, drawn to method of growing an organ comprising providing a cell, inserting a gene into the cell, growing the organ and placing the organ into a patient, classified in class 424, subclass 520.

68. Claims 170-175, drawn to method of growing an organ comprising providing a cell, inserting a gene into the cell, and treating with a growth factor, classified in class 424, subclass 520.

69. Claims 176, 180-182, drawn to method of growing an organ comprising providing a growth factor to a cell, classified in class 435, subclass 325.

70. Claims 176-178, drawn to method of growing an organ comprising providing a cell and adding a gene, classified in class 514, subclass 44.

71. Claims 179, drawn to method of growing an organ comprising providing a growth factor to a cell, growing the organ, and placing the organ into the patient, classified in class 435, subclass 325.

72. Claims 183, 184, drawn to method of treating autoimmune disease comprising administering a growth factor, classified in class 424, subclass 85.1.

73. Claims 183, 185-188, drawn to method of treating autoimmune disease comprising administering a gene, classified in class 514, subclass 44.

74. Claims 189-191, 193, drawn to method of treating inflammatory disease comprising administering a growth factor, classified in class 424, subclass 85.1.

75. Claims 189, 192, 194, drawn to method of treating inflammatory disease comprising administering a gene, classified in class 514, subclass 44.

76. Claims 195, 198, 200, 201, drawn to method of restoring function of an organ comprising administering growth factor, classified in class 424, subclass 85.1.

77. Claims 195-197, drawn to method of restoring function of an organ comprising administering cells, classified in class 424, subclass 520.

78. Claims 195, 199, 202-203, drawn to method of restoring function of an organ comprising administering genes, classified in class 514, subclass 44.

79. Claims 204, 205, drawn to method of growing a new portion of a pre-existing organ comprising administering a growth factor to produce muscle, classified in class 424, subclass 85.1.

80. Claims 204, 206, drawn to method of growing a new portion of a pre-existing organ comprising administering a cell to produce muscle, classified in class 424, subclass 520.

81. Claims 204, 207, drawn to method of growing a new portion of a pre-existing organ comprising administering a gene to produce muscle, classified in class 514, subclass 44.

82. Claims 204, 208, drawn to method of growing a new portion of a pre-existing organ comprising administering a gene and a cell to produce muscle, classified in class 514, subclass 44.

83. Claims 209, 210, drawn to method of growing a new portion of a pre-existing organ comprising administering a growth factor to produce

muscle, and further comprising placing a growth factor to grow new arteries thereby reviving a dead portion of the organ, classified in class 424, subclass 85.1.

84. Claims 209, 211, drawn to method of growing a new portion of a pre-existing organ comprising administering a cell to produce muscle, and further comprising placing a growth factor to grow new arteries thereby reviving a dead portion of the organ, classified in class 424, subclass 85.1.

85. Claims 212-214 drawn to method of replacing a pre-existing hard tissue organ in a patient comprising administering a growth factor to grow a new organ and then removing the pre-existing organ, classified in class 424, subclass 85.1.

86. Claims 212, 213, 215 drawn to method of replacing a pre-existing tooth organ in a patient comprising administering a growth factor to grow a new organ and then removing the pre-existing organ, classified in class 424, subclass 85.1.

87. Claims 212, 213, 216 drawn to method of replacing a pre-existing soft tissue organ in a patient comprising administering a growth factor to grow a new organ and then removing the pre-existing organ, classified in class 424, subclass 85.1.

88. Claims 212, 213, 217 drawn to method of replacing a pre-existing heart tissue organ in a patient comprising administering a growth factor to grow

a new organ and then removing the pre-existing organ, classified in class 424, subclass 85.1.

89. Claims 218-220, 224, 225 drawn to method of replacing a pre-existing hard tissue organ in a patient comprising administering a growth factor to grow a new organ, classified in class 424, subclass 85.1.

90. Claims 218, 219, 221, 224, 226 drawn to method of replacing a pre-existing tooth tissue organ in a patient comprising administering a growth factor to grow a new organ, classified in class 424, subclass 85.1.

91. Claims 218, 219, 222, 224 drawn to method of replacing a pre-existing soft tissue organ in a patient comprising administering a growth factor to grow a new organ, classified in class 424, subclass 85.1.

92. Claims 218, 219, 223, 224 drawn to method of replacing a pre-existing heart tissue organ in a patient comprising administering a growth factor to grow a new organ, classified in class 424, subclass 85.1.

93. Claims 227, 228, 235 drawn to method of growing an organ and adjacent tissue in a patient comprising administering a growth factor, classified in class 424, subclass 85.1.

94. Claims 227, 229-235 drawn to method of growing an organ and adjacent tissue in a patient comprising administering a gene, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Regarding the Groups directed to methods: Each method Group I independent from the others because it requires administration of:

a) different agents (e.g., growth factor proteins, genes, cells, etc.),

b) administration to different patient populations (e.g., those suffering from diabetes or autoimmune disease or having damaged organs) or different cell culture regimens,

c) achievement of different midpoints and/or endpoints (e.g., growth of muscle or brain or bone or tooth), and

d) substantially different method steps (e.g., cell culturing, therapeutic administration of protein, gene therapy, surgery).

A search and examination of any method in addition to the elected method in one patent application would require a significant extension of the search required for examination of one elected method, resulting in an undue search burden. Additionally, the art recognizes these different methods as being extremely diverse, and many have different classification.

Groups 30, 31 and 47 are directed to products, specifically, heart, brain and a hybrid organ. These three Groups are independent and distinct since hearts, brains and hybrid organs are composed of highly diverse cell types. Each Group requires search of the art which is completely non-overlapping with the searches required for the others. Furthermore, those skilled in the art recognize the diversity f these organs.

The Inventions directed to products are independent and distinct from the inventions directed to methods, since the products do not require any particular method of being made, and can be made by diverse methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C Kemmerer

ECK
March 27, 2003